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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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06/20/2000

Maura Rooney

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EXAMINER

FOREMAN, JONATHAN M

ART UNIT

PAPER NUMBER

3736

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/04/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/597,179

Applicant(s)

ROONEY ET AL.

Examiner

Jonathan ML Foreman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22,25,28-30,32-39,57,58,60-89,96 and 97 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22,25,28-30,32-39,57,58,60-89,96 and 97 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP 08257136 A to Asano et al. in view of U.S. Patent No. 4,984,581 to Stice.

In regards to claim 32, Asano et al. discloses a guide wire including an elongate core (11) including a proximal end and a distal end; a continuous, unitary coil (21) exhibiting an outer diameter and an inner diameter, composed of a second material [0031], surrounding a portion of the core, and extending beyond the distal end of the core by a plurality of turns of the coil (Figure 8); and a polymeric tip (12) contacting and extending from a distal portion of the coil, wherein the tip connects to the core by a polymeric material provided within spaces between adjacent turns of the coil such that the polymeric material encloses at least an area inside the inner diameter of the coil and up to the outer diameter of the coil (Figure 8). The polymeric tip includes a radio-opaque material [0030]. Asano et al. discloses the core being composed of a shape memory alloy [0016], but fails to disclose the shape memory alloy being a nickel-titanium alloy. However, Stice discloses a guidewire having a shape memory alloy core comprising a nickel-titanium alloy (Col. 3, lines 42 – 51). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the core as disclosed by Asano et al. to include nickel-titanium as taught by Stice in

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order to allow the guide wire to deform under stress as it is moved through curved body channels, and recover to a strait configuration when the stress is removed (Col. 3, lines 56 – 62).

3. Claim 97 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP 08257136 A to Asano et al. in view of U.S. Patent No. 4,984,581 to Stice as applied to claim 32 above, and further in view of U.S. Patent No. 4,763,647 to Gambale.

In regard to claim 97, Asano et al. fails to disclose the coil having a plurality of turns including non-contacting adjacent turns defining spaces extending to an outer diameter of the adjacent turns such that the polymeric material entirely fills the spaces between the adjacent turns. Gambale discloses a guide wire having an elongate core and a coil surrounding a portion of the core. Gambale teaches varying the flexibility characteristics by modifying the spacing of the coil (Col. 3, lines 52 – 61). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coil as disclosed by Asano et al. to include desired spacing in order to arrive at a desired flexibility of the distal end region (Col. 3, lines 52 – 61). By modifying the spacing of the coil, spaces would be created between adjacent turns of the coil that would be filled by polymeric material (12) when immersed into the resin liquid [0032].

4. Claims 22, 25, 28, 30, 33 - 38, 57, 58, 60, 62 – 68, 70 - 74, 76 – 82 and 84 - 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 08257136 A to Asano et al. in view of U.S. Patent No. 4,984,581 to Stice and U.S. Patent No. 4,763,647 to Gambale.

In regards to claims 22, 25, 28, 30, 33 - 38, 57, 58, 60, 62 – 68, 70 - 74, 76 – 82 and 84 - 89, Asano et al. discloses a guide wire including an elongate core (11) including a proximal end and a distal end and a length having a constant diameter (Figure 8); a continuous, unitary coil (21) exhibiting an outer diameter and an inner diameter, composed of a second material [0031], surrounding a portion of the core, and extending beyond the distal end of the core by a plurality of

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turns of the coil (Figure 8); and a polymeric tip (12) contacting and extending from a distal portion of the coil, wherein the tip connects to the core by a polymeric material provided within spaces between adjacent turns of the coil such that the polymeric material encloses at least an area inside the inner diameter of the coil and up to the outer diameter of the coil. Asano et al. discloses the second material comprising stainless steel [0031]. The distal portion of the core is tapered (11a). The polymeric tip includes a radio-opaque material [0030]. The coil includes a coating. Asano et al. discloses the coating being lubricious [0018]. Asano et al. discloses the coating being colored [0013]. The coil has a circular cross-section. Asano et al. discloses the core being composed of a shape memory alloy [0016], but fails to disclose the shape memory alloy being a nickel-titanium alloy. Additionally, Asano et al. fails to disclose the coil surrounding the entire length of the core or having a rectangular cross-section. However, Stice discloses a guidewire having a shape memory alloy core comprising a nickel-titanium alloy (Col. 3, lines 42 – 51). Stice also discloses a coil being located only at the tip or extending the entire length of the core (Col. 2, lines 49 – 51) and having a rectangular cross-section (Col. 2, lines 44 – 49). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the core as disclosed by Asano et al. to include nickel-titanium as taught by Stice in order to allow the guide wire to deform under stress as it is moved through curved body channels, and recover to a strait configuration when the stress is removed (Col. 3, lines 56 – 62). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coil as disclosed by Asano et al. to include a coil as taught by Stice in that Stice discloses a coil surrounding a portion of the core and a coil surrounding the entire core and a coil having circular and rectangular cross-section (Col. 2, lines 44 – 49) as being functionally equivalent and therefor interchangeable. Additionally, Asano et al. fails to disclose the coil having a pitch that varies and the plurality of turns including non-contacting adjacent turns

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defining spaces extending to an outer diameter of the adjacent turns such that the polymeric material entirely fills the spaces between the adjacent turns. Gambale discloses a guide wire having an elongate core and a coil surrounding a portion of the core. Gambale teaches varying the flexibility characteristics by providing the coil with a pitch that varies (Col. 3, lines 52 – 61). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coil as disclosed by Asano et al. to include a pitch that varies in order to arrive at a desired flexibility of the distal end region (Col. 3, lines 52 – 61). By modifying the pitch of the coil, spaces would be created between adjacent turns of the coil that would be filled by polymeric material (12) when immersed into the resin liquid [0032].

5. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP 08257136 A to Asano et al. in view of U.S. Patent No. 4,984,581 to Stice and U.S. Patent No. 5,947,940 to Beisel and U.S. Patent No. 4,763,647 to Gambale.

In regards to claim 29, Asano et al. discloses a guide wire including an elongate core (11) including a proximal end and a distal end; a continuous, unitary coil (21) exhibiting an outer diameter and an inner diameter, composed of a second material [0031], surrounding a portion of the core, and extending beyond the distal end of the core by a plurality of turns of the coil (Figure 8); and a polymeric tip (12) contacting and extending from a distal portion of the coil, wherein the tip connects to the core by a polymeric material provided within spaces between adjacent turns of the coil such that the polymeric material encloses at least an area inside the inner diameter of the coil and up to the outer diameter of the coil [0032]. Asano et al. discloses the second material comprising stainless steel [0031]. The distal portion of the core is tapered (11a). The polymeric tip includes a radio-opaque material [0030]. Asano et al. discloses the core being composed of a shape memory alloy [0016], but fails to disclose the shape memory alloy being a nickel-titanium alloy.

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Additionally, Asano et al. fails to disclose the second material comprising a precipitation hardened alloy. However, Stice teaches a guide wire having a shape memory alloy core comprising a nickel-titanium alloy (Col. 3, lines 42 – 51). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the super elastic alloy core as disclosed by Asano et al. to include nickel-titanium as taught by Stice in order to allow the guide wire to deform under stress as it is moved through curved body channels, and recover to a strait configuration when the stress is removed (Col. 3, lines 56 – 62). Beisel discloses a precipitation hardened alloy as the coil material for aiding guide wire insertion into a patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the second material as disclosed by Asano et al. to include the precipitation hardened alloy as taught by Beisel to increase the coil stiffness and enhance torqueability. Furthermore, the selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). Additionally, Asano et al. fails to disclose the coil having a pitch that varies and the plurality of turns including non-contacting adjacent turns defining spaces extending to an outer diameter of the adjacent turns such that the polymeric material entirely fills the spaces between the adjacent turns. Gambale discloses a guide wire having an elongate core and a coil surrounding a portion of the core. Gambale teaches varying the flexibility characteristics by providing the coil with a pitch that varies (Col. 3, lines 52 – 61). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coil as disclosed by Asano et al. to include a pitch that varies in order to arrive at a desired flexibility of the distal end region (Col. 3, lines 52 – 61). By modifying the pitch of the coil, spaces would be created between adjacent turns of the coil that would be filled by polymeric material (12) when immersed into the resin liquid [0032].

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6. Claims 39, 69, 83 and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 08257136 A to Asano et al. in view of U.S. Patent No. 4,984,581 to Stice and US Patent No. 4,763,647 to Gambale as applied to claims 22, 57, 70 and 84 above, and further in view of U.S. Patent No. 5,174,302 to Palmer.

In regards to claims 39, 69, 83 and 96, Asano et al. in view of Stice and Gambale disclose a unitary coil (21) but fail to disclose the unitary coil comprising a multifilar wire. However, Palmer discloses a unitary coil comprising a multifilar wire (Col. 4, lines 17 – 27). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coil as disclosed by Asano et al. in view of Stice and Gambale to include a multifilar wire coil as taught by Palmer in order to create intermittent bands or regions of high radiopaqueness (Col. 4, lines 25 – 26) to aid in the visualization of the guidewire during a medical procedure.

7. Claim 75 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP 08257136 A to Asano et al. in view of U.S. Patent No. 4,984,581 to Stice and US Patent No. 4,763,647 to Gambale as applied to claim 70 above, and further in view of U.S. Patent No. 5,947,940 to Beisel.

In regards to claim 75, Asano et al. in view of Stice and Gambale discloses a guide wire including an elongate core (11) and a coil (21) composed of a second material surrounding a portion of the core, but fails to disclose the second material comprising a precipitation hardened alloy. Beisel discloses a guide wire including a precipitation hardened alloy as the coil material for aiding guide wire insertion into a patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coil of Asano et al. in view of Stice and Gambale to include the precipitation hardened alloy as taught by Beisel to increase the coil stiffness and enhance torqueability. Furthermore, the selection of a known material based upon its suitability for

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the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

8. Claim 61 is rejected under 35 U.S.C. 103(a) as being unpatentable over JP 08257136 A to Asano et al. in view of U.S. Patent No. 4,984,581 to Stice and U.S. Patent No. 4,763,647 to Gambale and U.S. Patent No. 5,947,940 to Beisel.

In regards to claim 61, Asano et al. discloses a guide wire including an elongate core (11) including a proximal end and a distal end and a length having a constant diameter (Figure 8); a continuous, unitary coil (21) exhibiting an outer diameter and an inner diameter, composed of a second material [0031], surrounding a portion of the core, and extending beyond the distal end of the core by a plurality of turns of the coil (Figure 8); and a polymeric tip (12) contacting and extending from a distal portion of the coil, wherein the tip connects to the core by a polymeric material provided within spaces between adjacent turns of the coil such that the polymeric material encloses at least an area inside the inner diameter of the coil and up to the outer diameter of the coil [0032]. Asano et al. discloses the core being composed of a shape memory alloy [0016], but fails to disclose the shape memory alloy being a nickel-titanium alloy. However, Stice discloses a guidewire having a shape memory alloy core comprising a nickel-titanium alloy (Col. 3, lines 42 – 51). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the core as disclosed by Asano et al. to include nickel-titanium as taught by Stice in order to allow the guide wire to deform under stress as it is moved through curved body channels, and recover to a strait configuration when the stress is removed (Col. 3, lines 56 – 62). Additionally, Asano et al. fails to disclose the plurality of turns of the coil including non-contacting adjacent turns defining spaces extending to an outer diameter of the adjacent turns such that the polymeric material entirely fills the spaces between the adjacent turns. Gambale discloses a guide wire having an

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elongate core and a coil surrounding a portion of the core. Gambale teaches varying the flexibility characteristics by providing the coil with spaces between adjacent turns of the coil (Col. 3, lines 52 – 61). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coil as disclosed by Asano et al. to include spaces in order to arrive at a desired flexibility of the distal end region (Col. 3, lines 52 – 61). The spaces between adjacent turns of the coil would be filled by polymeric material when immersed in the liquid resin [0032]. Asano et al. fails to disclose the second material comprising a precipitation hardened alloy. Beisel discloses a guide wire including a precipitation hardened alloy as the coil material for aiding guide wire insertion into a patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the coil of Asano et al. to include the precipitation hardened alloy as taught by Beisel to increase the coil stiffness and enhance torqueability. Furthermore, the selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

Response to Arguments

9. Applicant's arguments filed 10/6/06 have been fully considered but they are not persuasive. Applicant's request that the next action be made final in order to clarify the status of claim 32 has been denied. In the Office Action Summary form PTOL-326 accompanying the July 7, 2006 Office Action, claim 32 is properly shown as rejected. The Examiner inadvertently left "32" out of the statement regarding which claims were rejected. However, each of the claim limitations present in claim 32 were addressed in section 3 of the Office Action.

Applicant asserts that one having ordinary skill in the art at the time the invention was made would not have been motivated by Gambale to modify the spacing of the coil as disclosed by Asano et al. However, the Examiner disagrees. Although, Asano et al. fails to discuss enhancing the

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flexibility of the guide wire, Gambale teaches that the spacing of a distal coil can be modified to achieve a desired flexibility. Thus, one having ordinary skill in the art would have been motivated by the disclosure of Gambale to modify the spacing of the coil as disclosed by Asano et al. in order to achieve a desired flexibility of the distal end of the guidewire. Applicant asserts that increasing the pitch of the coil would result in very few turns of a coil, and that with less turns, the ability of coil to adhere resin is lessened. However, modifying the pitch (i.e. spacing) of the coil does not equate to reducing the number of coils.

Conclusion

10. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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